Stop TB Partnership

BRIEF

(As of July 14, 2021)

AN URGENT NEED FOR A NEW EFFECTIVE, EFFICIENT AND AFFORDABLE TB VACCINE

Tuberculosis (TB) has been the deadliest infection faced by humanity, claiming a billion lives in the past 200 years.[1]

The World Health Organization (WHO) End TB Strategy[2], endorsed by the World Health Assembly in 2014, calls for an effective new vaccine to end TB. In order to rapidly decline the incidence of TB and meet the Sustainable Development Goal target of ending TB, an effective vaccine will be required, especially in the period after 2025 when TB incidence needs to decline at a pace that is at least eight times higher than the current rate of decline of 2% per annum. This pace of decline in incidence will require new tools and especially scaling up of prevention in addition to diagnosis and treatment of TB. An effective vaccine in the TB prevention toolkit is essential as other tools like TB preventive therapy have limitations for use at scale in the general population.

At the United Nations High-Level Meeting on TB[3] in 2018, world leaders committed to delivering new, effective, safe, equitable and affordable TB vaccines "as soon as possible." In 2020, the United Nations Secretary General's report[4] on TB highlighted the need for a vaccine and called for substantially increased investments in TB research to drive technological breakthroughs, including for a vaccine.

Unfortunately, the COVID-19 pandemic has further pushed back progress on the global fight against TB by up to 12 years.[5] However, vaccines developed for COVID-19 at great speed provide hope that the slow-moving TB vaccines development process can be fast-tracked with strong political commitment, adequate funding and faster research techniques.

What about the existing vaccine?

There is currently only one TB vaccine—the Bacillus Calmette-Guérin (BCG) vaccine—in existence, and it is precisely 100 years old. The vaccine protects against severe forms of TB in infants and young children but offers mostly poor protection against other forms of TB, TB transmission and disease in adolescents and adults. It is thus not surprising that despite

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[1] Paulson, T. Epidemiology: A mortal foe. Nature 502, S2–S3 (2013). https://doi.org/10.1038/502S2a https://www.nature.com/articles/502S2a
[2] WHO. The End TB Strategy. https://www.who.int/teams/global-tuberculosis-programme/the-end-tb-strategy
[3] UNGA October 2018. Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/3
[4] Report of the UNSG. 16 September 2020. UNGA A/75/236. https://undocs.org/en/A/75/236
[5]http://www.stoptb.org/webadmin/cms/docs/Release%20for%20COVID%20and%20TB%202021%20report%20draft_16%20March_FINAL.pdf

universal infant BCG vaccination in TB-endemic countries, an estimated 10 million people developed TB in 2019.

Funding needed for TB vaccine research and development

The Stop TB Partnership's Global Plan[6] estimates that at least **US$550 million** per year is needed to develop efficient and effective TB vaccines. In 2019, TB vaccine research and development received only US$117 million, which is the highest ever annual funding but still grossly insufficient.[7] Funding constraints are one of the major reasons why progress on TB vaccines has been slow. By comparison, COVID-19 vaccine research has received over **US$100 billion** in funding over the past year that as of July 2021 has resulted in 14 approved vaccines.[8] Adequate funding for TB vaccines and the application of faster research techniques, as was done for COVID-19 vaccines, could be a game-changer for a much-needed breakthrough in TB vaccine development.

The pipeline for new TB vaccines

There are currently 14 candidate TB vaccines in different stages of development. Now there is also a possibility to use the messenger RNA (mRNA) technique—being widely used for COVID-19 vaccines—for TB vaccines. The infographic below summarizes the 14 candidate vaccines.9

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[6] Stop TB Partnership. Global Plan to End TB 2018-2022. http://www.stoptb.org/assets/documents/global/plan/GPR_2018-2022_Digital.pdf

[7] TAG and Stop TB Partnership 2020. Tuberculosis Research Funding Trends, 2005–2019 https://www.treatmentactiongroup.org/wp-content/uploads/2020/12/tbrd_2020_final_web.pdf

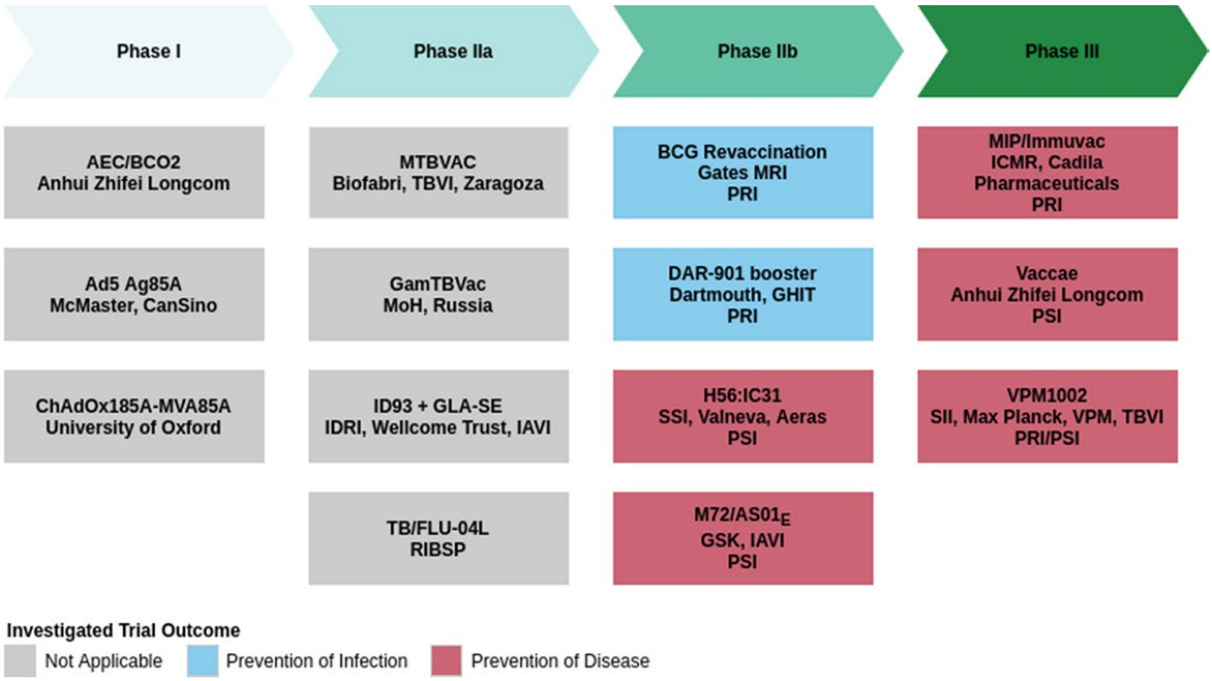
[8] https://www.businesswire.com/news/home/20210110005098/en/Governments-Spent-at-Least-%E2%82%AC93bn-on-COVID-19-Vaccines-and-Therapeutics-During-the-Last-11-Months

[9] C. K. Weerasuriya, R. A. Clark, R. G. White, R. C. Harris. New tuberculosis vaccines: advances in clinical development and modelling. Journal of Internal Medicine, Volume: 288, Issue: 6, Pages: 661-681, First published: 31 October 2020 https://onlinelibrary.wiley.com/doi/epdf/10.1111/joim.13197

[9]Knight, G. M., Griffiths, U. K., Sumner, T., Laurence, Y. V., Gheorghe, A., Vassall, A., et al. (2014). Impact and cost-effectiveness of new tuberculosis vaccines in low- and middle-income countries. *Proc. Natl. Acad. Sci U.S.A.* 111, 15520–15525. doi: 10.1073/pnas.1404386111

Harris, S. T., and White, R. (2018). "RG. The potential epidemiological impact of new TB vaccines," in *Proceedings of the TB Science at the 49th Union World Conference on Lung Health*, The Hague.

[10] The lightning-fast quest for COVID vaccines — and what it means for other diseases. https://www.nature.com/articles/d41586-020-03626-1

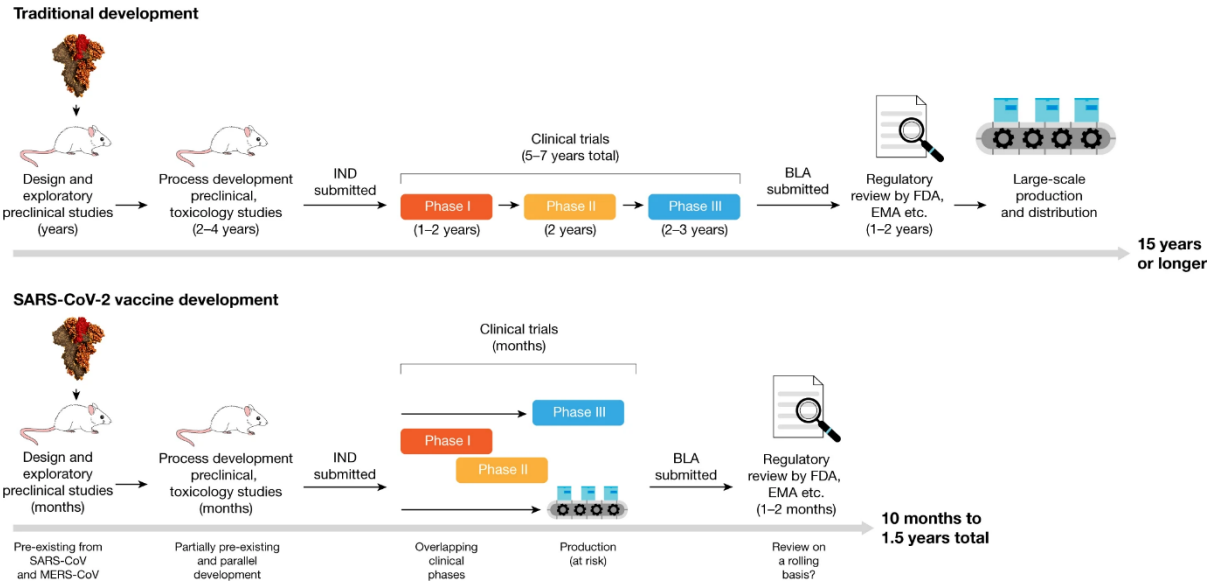


Developing a new vaccine for use in mass campaigns to prevent pulmonary TB among adolescents and adults will be necessary to interrupt the cycle of TB transmission in the short- and medium-term. In contrast, some combination of infant and adolescent/adult vaccination approaches would likely be optimal to sustain long-term TB control.[10]

Learnings from the COVID-19 vaccine development

The COVID-19 vaccine research pipeline has shown that with adequate political will and increased investment in all phases of research and development of an access plan, the scientific research community can find the ability and capacity to fast-track all processes to beat the odds. New ways of making vaccines, such as by using mRNA, have been validated by the COVID-19 response and have shown that the development process can be accelerated substantially without compromising safety. mRNA technology is revolutionizing vaccinology: Candidate mRNA vaccines can be chemically synthesized in a few days.[10] The world should apply the same urgency to develop ready-to-use vaccines for TB.

[10] Ibid



Source: https://www.nature.com/articles/s41586-020-2798-3

COVID-19 vs. Tuberculosis Vaccines

	COVID-19	*Tuberculosis*
Pathogen discovered	2019	1882
Vaccine developed	2020	1921
Annual deaths (2020)	2 million	1.9 million*
Numbers of vaccines approved by WHO (by June 2021)	8	1 (only effective for children)
Global investments in vaccines	$107 billion**	$ 0.117 billion***

Number of vaccine candidates	109	14

***estimated**
**** Funding as of January 2021**
*****Annual funding in 2019**

Sources:
a) https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf
b)https://www.businesswire.com/news/home/20210110005098/en/Governments-Spent-at-Least-%E2%82%AC93bn-on-COVID-19-Vaccines-and-Therapeutics-During-the-Last-11-Months
c) https://www.treatmentactiongroup.org/wp-content/uploads/2020/12/tbrd_2020_final_web.pdf